CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE MEETING
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PUBLIC COMMENT

Comment by:

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Binax is a small medical device company in Portland, Maine, which manufactures Rapid Diagnostic Test devices. My comments relate to the CLIA Waiver process, both in the context of my company, and also general comments about the process. Binax currently has applications for two products submitted for CLIA Waiver. Products detect *Legionella pneumophila* and *Streptococcus pneumoniae.* These applications were submitted in 1998 and 1999, and during this time we have had extensive communication with the CDC and FDA and the CMS. Without going into extensive detail, I will say that Binax has answered all inquiries from both FDA and CDC, and has expended resources, which are sometimes limited in a small company, to perform additional studies requested.

Unfortunately, Binax is still waiting for a response regarding the status of our Waiver applications. While we remain hopeful for a positive outcome for our applications, there are some general comments I have about the Waiver process.

As this Committee continues their input into the Waiver process, I ask you to consider two things: the impact of the regulation on manufacturer's and the impact of the regulation on the public health.

Regarding the impact on manufacturer's, we ask for:

- Timely response to our applications and inquiries
- Clear criteria on accuracy so manufacturer's can measure the likelihood of success prior to spending time and resources
- Equitable application of the Waiver criteria to all submissions

Regarding the public health, I ask you to consider the positive impact that products with Waived status can have on the public health.

- Rapid diagnosis leads to early treatment, which definitely effects public health
- Rapid diagnosis of specific organisms can lead to proper treatment with the right antibiotic, which has implications on the problems we face with antibiotic resistance.